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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,056	09/21/2005	Jamila Najib	BJS-3665-153	6402

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
RAO, SAVITHA M	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,056	NAJIB, JAMILA	
	Examiner	Art Unit	
	SAVITHA RAO	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/12/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-19 are pending and are subject of this office action. Receipt is acknowledged of a preliminary amendment filed on 10-27-2006 in which claims 3 & 5-9 were amended and new claims 11-20 were added.

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statement filed 07/12/2005. The Examiner has considered the reference cited therein to the extent that each is a proper citation. Please see the attached USPTO Form 1449.

. The "International Search Report (French)" on 1449 dated 07/12/2005 has been lined out because it is not a published document and therefore cannot have a date of publication which is required for a citation in the non-patent document area of 1449.

Election/Restrictions

Applicant's election of Group 1 (claims 19-36) drawn to a method of treatment of a pathology involving a deregulation of lipid and/or glucose metabolism, in the reply filed on 06/13/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election of invention of Group I has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's election of species of arthrosclerosis as a single pathology and the compound of example 11, as a single species of compounds of formula (I) with traverse

is acknowledged. The traversal is on the ground(s) that the examiner has not demonstrated that the species would be classified "in different classification".

Examiner has considered the applicant's arguments. However, upon further consideration, **examiner withdraws the specie election** for the compound and the specific pathological condition. Accordingly no claims are withdrawn and claims 19-26 are under consideration in the instant election.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 19-26 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some of the pathologies not reasonably provide enablement for all the pathologies involving a deregulation of lipid and/or glucose metabolism with all of the compounds encompassed by general formula I (See claim 19) The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. These is a scope of enablement rejection

To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fd. Cir. 1993). Explaining

what is meant by "undue experimentation," the Federal Circuit has stated that:
The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996). As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing Ex parte Forman, 230 USPQ 546 (Bd. Apls. 1986) at 547 the court recited eight factors: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance provided, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability of the art, and (8) the breadth of the claims..

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

(1) The nature of the invention: Claims 19-26 recite a method for treating a pathology

involving a deregulation of lipid and/or glucose metabolism by administering an effective amount of the compound represented by formula I (see claim 19), The invention is complex in that it involves the treatment of a pathologies involving a deregulation of lipid and/or glucose metabolism with the compounds of formula (I) which encompasses numerous compounds. Moreover, pathologies of lipid/glucose metabolism are numerous and are responsible for various conditions and disorders. Deregulation of glucose metabolism results in severe pathophysiological conditions such as diabetes mellitus, sleep apnea (Punjabi et al , J Appl Physiol 99, 1998-2007 (2005) and memory impairment (Ouchi et al. Additionally Merck Manual (Lipid metabolism, Hereditary metabolic disorders, Merck Manual Home Edition, 2003) teaches conditions caused by deregulation of lipid metabolism such as Gaucher's disease where in glucocerbrosides that are product of fat metabolism accumulates in tissues (page 1, left col., 1st paragraph), Wolman's disease where specific types of cholesterol and glycerides accumulates in tissues (page 1, right col. 1st paragraph).

(2) The state and predictability of the art: The state of art regarding treating various pathologies associated with deregulation of lipid/glucose metabolism is high. However, the state of art for the treatment of all the different pathologies associated with lipid/glucose metabolism with all the compounds of general formula (I) is underdeveloped.

(3) The relative skill of those in the art: The relative skill of those in the art is high,

(4) The breadth of the claims: The claims are extremely broad in that they encompass literally all the pathologies associated with lipid/glucose metabolism. Moreover, the claims encompass numerous compounds and the treatment of all the pathologies associated with deregulation of lipid/glucose metabolism with the plurality of claimed compounds.

(5) The amount of direction or guidance provided and the presence or absence of working examples: In the instant case, working examples are provides demonstrating the activity of a subset of claimed compounds (examples 2-23) on several in-vitro assays and in-vivo assays which are predictive of lipid and glucose metabolism. One example is example 25 which details testing of compounds examples 2-23 for their effect on activation of PPAR in vitro in RK13 fibroblast cell lines and the results indicated that the compounds were capable of very potent activation of the PPAR alpha nuclear receptor (instant specification, page 84). Another example is example 26 which recites the in-vivo testing to evaluate the effect of the compounds on lipid metabolism with examples of compounds 2--23, however, only compound of example 11 was tested for the effect on total cholesterol and triglycerides in an in-vivo study (instant specification, page 88). Still another example is example 32: the evaluation on metabolic syndrome and diabetes in an in-vivo model which tests instantly claimed compounds 2-23 (instant specification, page 100). However, there are a lack of working examples presented in the specification as filed showing how to treat all the

pathologies associated with lipid/glucose metabolism, with all the compounds of general formula (I) encompassed in claim 1. For example, the compound of formula (I) has many possible substitutions that can be applied to G1, G2, G3, and R1, R2, and R3, thereby leading to distinct chemical compounds. Because each compound is distinct structurally, each compound may have different reactivity, solubility, oral bioavailability, efficacy etc. Note that lack of a working example is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP § 2164.

(6) The quantity of experimentation necessary: In the absence of experimental evidence commensurate in scope with the claims, the skilled artisan would not accept that any compound of formula I could be predictably used in the treatment for all the pathologies associated with lipid/glucose metabolism. Selecting the proper compound for the proper disease, would require screening those compounds in assays known to correlate with to clinical efficacy of such treatments, and formulation into a dosage form. This is undue experimentation given the limited guidance and direction provided by Applicants.

Accordingly, the inventions of claims 19-26 do not comply with the scope of enablement requirement of 35 U.S.C 112, first paragraph, since to practice the claimed invention a person of ordinary skill in the art would have to engage in undue experimentation with no assurance of success.

Conclusion

Claims 19-26 are rejected. No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-5315. The examiner can normally be reached on Mon-Fri 7 am to 4 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAVITHA RAO/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614